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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,827	09/07/2004	Janusz B. Pawliszyn	PAT 804W-2	8910
26123 7590 05/29/2007 BORDEN LADNER GERVAIS LLP WORLD EXCHANGE PLAZA 100 QUEEN STREET SUITE 1100 OTTAWA, ON K1P 1J9 CANADA			EXAMINER DIRAMIO, JACQUELINE A	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 05/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/506,827	PAWLISZYN, JANUSZ B.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 101-107, 109 and 118-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 101-107, 109 and 118-121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/23/2007</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2007 has been entered.

### ***Status of the Claims***

Applicant's amendments to claims 101 – 103 are acknowledged, as well as the addition of new claims 120 and 121.

Currently, claims 101 – 107, 109, and 118 – 121 are pending.

### ***Withdrawn Rejections***

All previous rejections of the claims under 35 U.S.C. 103(a) have been withdrawn in view of Applicant's amendments and arguments filed March 14, 2007.

### ***Response to Arguments***

Applicant's arguments, see p11-19, filed March 14, 2007, with respect to the rejection(s) of claim(s) 101 under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395) have been fully

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considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration of the Pompidou et al. reference, a new ground(s) of rejection is made and presented below.

## **NEW GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 101 – 103, 106, 109, and 119 – 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510).

Pompidou et al. teach a device for in situ analysis of a substrate, wherein the substrate includes an animal or animal tissue, said device comprising:

at least one microsystem 2 (fibre) having a hydrogel coating (coated end) which is at least partially coated with specific antibodies 4 (an extraction phase) for binding (extracting) an antigen (component) present in the substrate; and

a guidance system (positioning device) for guiding said coated end into position within the animal or animal tissue, said guidance system comprising:

an exploration system 5 (catheter) for placement within an animal or animal tissue through which said microsystem extends, said exploration system having an open end for positioning within said animal or animal tissue and said exploration system being immobilized during sampling with respect to the animal or animal tissue; and

a flexible rod 1 and rigid support 3 (fibre holding region) attached to said microsystem, said flexible rod and support being movable with respect to the exploration system, to move said coated end of the microsystem into or out of the animal or animal tissue;

wherein said microsystem is a flexible ribbon (wire) (see Figures 1, and 3-5; and column 1, lines 8-12 and lines 35-65; column 2, lines 2-56; column 3, lines 6-10 and lines 43-59; column 4, lines 4-19 and lines 49-64; column 5, lines 5-19 and lines 40-54; column 6, lines 13-17; and column 8, lines 58-67).

However, Pompidou et al. fail to teach that the fiber, i.e. microsystem, is coated with a polymeric extraction phase.

Gourley et al. teach a sensor device comprising an optical fiber for use in sensing the concentration of a component in a medium. The optical fiber 12 contains a sensing

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element 18, which comprises a coating of a polymeric matrix. The polymeric matrix, which preferably comprises dimethylsiloxane polymers, allows for permeability of the component the concentration of which is to be determined or measured by the sensor system. The fiber and sensing element further contain an overcoating 20, which preferably comprises a cellulosic material (derivatized cellulose). The sensor system is created in order to allow for it to be suitable for use in vivo in a human patient.

Additionally, the fiber and sensing element utilizes an optical indicator, preferably a fluorescent dye, which is sensitive to the component of interest and allows for determination of the concentration of the component. Further, the system utilizes one or more optical fibers, which allows for measuring a plurality of different components of interest (see Figure 1; and column 2, lines 60-65; column 3, lines 62-68; column 4, lines 1-60; column 6, lines 39-55; column 7, lines 34-58; and column 9, lines 5-68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. the use of a polymeric matrix coating as an extraction phase as taught by Gourley et al. because Gourley et al. teach the benefit of coating a sensor system with a polymeric matrix coating in order to allow for permeability of the component of interest to be measured.

With respect to Applicant's claims 102 – 103, it would have been obvious to include an additional coating of a biocompatible layer, such as a cellulosic material, as taught by Gourley et al. because Gourley et al. teach the benefit of including a cellulosic

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coating with a sensor system in order to allow for the sensor to be suitable for use in vivo in a human patient.

With respect to Applicant's claim 106, it would have been obvious to use a fluorescent indicator with the extraction phase as taught by Gourley et al. because Gourley et al. teach that the indicator is sensitive to the component of interest and therefore, allows for determination of the concentration of the component.

With respect to Applicant's claims 109 and 119, it would have been obvious to use multiple fibers as taught by Gourley et al. because Gourley et al. teach the benefit of multiple fibers in order to allow for measuring a plurality of different components of interest.

With respect to Applicant's claim 120, Gourley et al. teach that the polymeric matrix preferably comprises dimethylsiloxane polymers (see column 4, lines 24-57).

With respect to Applicant's claim 121, Pompidou et al. teach the immobilization of an antibody as a bioaffinity agent to the microsystem in order to selectively bind to an antigen of interest (see Figure 2; and column 2, lines 16-44).

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510), as applied to claim 101 above, and further in view of Colburn et al. (US 2003/0183758).

The device of Pompidou et al. meets the structural limitations of both the fiber and extraction phase, therefore, enabling the device to be useful in a variety of

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analytical instruments, however, Pompidou et al., as well as Gourley et al., fail to teach the use of MALDI-TOFMS analysis specifically.

Colburn et al. teach that matrix-assisted laser desorption/ionization (MALDI) in combination with time-of-flight (TOF) analyzers have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers (see paragraph 0003, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the MALDI-TOFMS combination as taught by Colburn et al. as the analytical instrument for the device of Pompidou et al. and Gourley et al. because Colburn et al. teach the benefit of using MALDI-TOF analyzers because they have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510), as applied to claim 101 above, and further in view of Riviere et al. (US 2003/0180954).

Pompidou et al. and Gourley et al. further fail to teach the addition of a calibrant to the extraction phase of the fiber.

Riviere et al. teach the use of polydimethylsiloxane coated fibers as skin-imitating membranes in order to study permeation of chemicals into these membranes (see



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paragraph 0037). The absorption parameters, referred to as molecular descriptors, of each chemical compound is obtained by comparing to its calibration standard, wherein the standards were created by analyzing fifty compounds and their subsequent molecular descriptors (see paragraphs 0167-0169). The calibration standards determine the system constants, which reflect the properties of the membrane (fibers) and will not change with different solutes, therefore, the molecular descriptors of unknown/study compounds can be obtained (see paragraph 0170).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the extraction phase of the microsystem of Pompidou et al. and Gourley et al. a calibration standard (calibrant) as taught by Riviere et al. because Riviere et al. teach the benefit of using calibration standards to determine the system constants because they reflect the properties of the fibers, which will not change and thus enable the absorbance of unknown compounds to be studied.

Claims 107 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510), as applied to claim 101 above, and further in view of Pawliszyn (US 5,691,206).

Pompidou et al. and Gourley et al. fail to teach that the device comprises an openable housing for said microsystem (fiber), wherein said housing can comprise a needle.

Pawliszyn teaches a device for solid phase microextraction comprising a fiber 6, which contains a polymeric coating selective for a component of interest (extraction

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phase), and a metal sleeve 24 and hollow needle 18, which houses the fiber. The purpose of the housing of the fiber by the metal sleeve and hollow needle is to protect the fiber from damage when not in use. The device is enabled for solid phase microextraction in both in-vivo and in-vitro samples, wherein said polymeric coating is chosen based on its selectivity for a target component present in a sample carrier (see Figures 1 and 2; and column 2, lines 10-21; column 3, lines 5-16; column 5, lines 10-15; and column 7, lines 33-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. and Gourley et al. an openable housing comprising a needle for housing the microsystem (fibre) as taught by Pawliszyn because Pawliszyn teaches the benefit of housing a fiber for use in in-vitro or in-vivo sampling for extraction purposes in order to protect the fiber from damage when not in use.

### ***Conclusion***

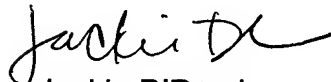
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jackie DiRamio  
Patent Examiner  
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